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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,140	11/16/1999	BEKA SOLOMON	27/150	3910

1444 7590 09/17/2004

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EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/441,140	SOLOMON, BEKA	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 150-172* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4* is/are allowed.

6)☒ Claim(s) *150,151,156,157,162,163,168 and 169* is/are rejected.

7)☒ Claim(s) *152-155, 158-161, 164-167, and 170-172* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8.9.04,2.23.04*. 8/18/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. **The instant Office Action replaces the Office Action mailed 10 September 2004.**

2. The Response and Amendment filed 9 August 2004 has been received and entered in full.

3. The Response and Amendment filed 18 August 2004 has been received and entered in full.

4. The Amendment filed 26 April 2004 has been received and entered in full.

5. Exhibits A, B, C, and D filed 9 August 2004 have been received and taken into consideration.

6. The Declaration pursuant to 37 C.F.R. §1.175 filed 25 August 2004 has been received and entered in full.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

8. The Objection to the Claims as set forth at pp. 4 ¶18 in the previous Office Action (10 June 2004) is hereby *withdrawn* in view of Applicant's amendments (9 August 2004).

9. The Rejection of claims **150-167** under 35 U.S.C. §112 ¶1 as set forth at pp. 4-13 ¶19-43 in the previous Office Action (10 June 2004) is *withdrawn* in view of Applicant's Exhibits, Declaration, and arguments (9 August 2004).

Claim Objections

10. Claims **152-155, 158-161, 164-167,** and **170-172** are objected to because of the following informalities: said claims depend from rejected claims. Appropriate correction is required.

Maintained Objections And/Or Rejections

11. Claims **150, 151, 156, 157, 162, 163, 168,** and **169** are rejected under 35 U.S.C. 102(a) as being anticipated by Bickel *et al.* (March/April 1994) "Development and in Vitro Characterization of a Cationized Monoclonal Antibody against βA4 Protein: A Potential Probe for Alzheimer's Disease." Bioconjugate **5**(2): 119-125 for the reasons as set forth at pp. 13-14 ¶44-47 in the previous Office Action (10 June 2004).

12. Applicant traversed the rejection of the claims in the Response filed (9 August 2004) on the following grounds: **(a)** the claims require the antibody to be in a "pharmaceutical formulation" (Exhibit A) and **(b)** Bicker *et al.* uses a Tris solution which is not a "pharmaceutically acceptable carrier" (Exhibit C).

13. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

14. On "**(a)**", Applicant's arguments are most analogous to *In re Ngai*, 70 USPQ2d 1862 (CA FC 2004) where a claim directed to kit for performing method of normalizing and amplifying ribonucleic acids was properly rejected as anticipated by prior art, even though content of instructions in claimed kit differs from instructions in prior art, since addition of new set of instructions into known kit merely teaches new use for existing product, in that instructions do not interrelate with kit so as to produce new product, and since addition of printed matter to existing product will not distinguish invention from prior art in terms of patentability if printed matter is not functionally related to product.

15. In the instant case, Applicant has provided a new pharmaceutical formulation of a known monoclonal antibody, the AMY33. By Applicant's definition: "<pharmacology> The mixture or prescribed recipe for packaging a protein pharmaceutical, the process of developing such a formulation." (Response filed 9 August 2004, pp. 8; Exhibit A), the definition of "pharmaceutical" may either be a "mixture" or a "prescribed recipe". As noted in *In re Ngai*, printed matter to an existing product will not distinguish invention from prior art in terms of patentability if printed matter is not functionally related to product.

16. The second component of the term "pharmaceutical" is the "mixture" or the "packaging" in the form of a solution or composition. As evident from Bickel *et al.*, therapeutic use is not the only applicable use of the AMY-33 monoclonal antibody, therefore cannot be limiting.
In addition, a preamble is not a limitation where the claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the

claim {see MPEP §2111.02[R-2]}. The claims recite functional properties assigned to the claimed antibody including "inhibits β-amyloid aggregation" and/or "maintains soluble β-amyloid solubility". The AMY33 antibody as taught by Bickel *et al.* is the same antibody as instantly claimed. Since a compound and all of its properties are inseparable, although Bickel *et al.* is silent on said properties they are taken to be the same antibodies (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Therefore by adding the "pharmaceutical formulation" limitation, Applicant is providing a new use for an existing product.

17. On "**(b)**", Tris is a known buffer. Voet & Voet Biochemistry (2nd Ed.) "Chapter 2: Aqueous Solution" teaches that the physiological pH of human blood is 7.4 (pp. 37). Therefore the solution taught by Bickel *et al.* is not inconsistent with use as a pharmaceutical as it is at physiological pH. Applicant's Material Safety Data Sheet (MSDS; Exhibit C) is to describe Tris powder, not a buffered Tris solution at pH=7.4.

18. Claims **150, 151, 156, 157, 162, 163, 168,** and **169** are rejected under 35 U.S.C. 102(b) as being anticipated by Stern *et al.* (May 1989) "Monoclonal antibodies to a synthetic peptide homologous with the first 28 amino acids of Alzheimer's disease beta-protein recognize amyloid and diverse glial and neuronal cell types in the central nervous system." Am J Pathol. 1989 **134**(5): 973-978 for the reasons as set forth at pp. 14-15 ¶48-51 in the previous Office Action (10 June 2004).

19. Applicant traversed the rejection of the claims in the Response filed (9 August 2004) on the following grounds: **(a)** Stern *et al.* does not teach or make obvious a pharmaceutical

formulation or not use the AMY-33 antibody as a therapeutic and **(b)** the commercially available solution of AMY33 from Sigma contains sodium azide (Exhibits B & D).

20. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

21. On "**(a)**", Applicant's arguments are most analogous to *In re Ngai*, 70 USPQ2d 1862 (CA FC 2004) where a claim directed to kit for performing method of normalizing and amplifying ribonucleic acids was properly rejected as anticipated by prior art, even though content of instructions in claimed kit differs from instructions in prior art, since addition of new set of instructions into known kit merely teaches new use for existing product, in that instructions do not interrelate with kit so as to produce new product, and since addition of printed matter to existing product will not distinguish invention from prior art in terms of patentability if printed matter is not functionally related to product.

22. In the instant case, Applicant has provided a new pharmaceutical formulation of a known monoclonal antibody, the AMY33. By Applicant's definition: "<pharmacology> The mixture or prescribed recipe for packaging a protein pharmaceutical, the process of developing such a formulation." (Response filed 9 August 2004, pp. 8; Exhibit A), the definition of "pharmaceutical" may either be a "mixture" or a "prescribed recipe". As noted in *In re Ngai*, printed matter to an existing product will not distinguish invention from prior art in terms of patentability if printed matter is not functionally related to product.

23. The second component of the term "pharmaceutical" is the "mixture" or the "packaging" in the form of a solution or composition. As evident from Stern *et al.*, therapeutic use is not the only applicable use of the AMY-33 monoclonal antibody, therefore cannot be limiting.

24. In addition, a preamble is not a limitation where the claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim {see MPEP §2111.02[R-2]}. The claims recite functional properties assigned to the claimed antibody including "inhibits β-amyloid aggregation" and/or "maintains soluble β-amyloid solubility", but the AMY33 antibody as taught by Stern *et al.* is the same antibody as instantly claimed as evidenced by the Declaration by Beka Solomon filed 9 August 2004 (2nd paragraph, pp. 4). Since a compound and all of its properties are inseparable, the AMY-33 antibody as taught by Stern *et al.* and instantly claimed are the same antibodies as is clear from the Inventor's admission on the record (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)).

25. On "**(b)**", no evidence is present that Stern *et al.* purchased the AMY33 monoclonal antibody from Sigma. Nor does Stern *et al.* teach that the ELISA solution contains sodium azide. In fact, Stern *et al.* clearly states that the antibodies were generated per Lee *et al.* (March 1988) "Identification of the major multiphosphorylation site in mammalian neurofilaments." Proc Natl Acad Sci U S A. **85**(6): 1998-2002 in the "Materials and Methods" section (pp. 974).

26. In addition, hazardous preservatives such as azide interfere with antibody-antigen binding interactions thus are not desirous to have in an antibody solution for ELISA (see ScyTek Laboratories website; retrieved on 3 September 2004). The standard antibody solution for performing immunocytochemistry (including ELISA) is PBS which is 1 mM KH_2PO4, 3 mM $Na_2HPO_4 \cdot 7H_20$, pH 7.4, and 155 mM NaCl (see Gibco Media Formulations from Invitrogen website; retrieved 3 September 2004). Therefore PBS, the standard ELISA solution, is almost

identical to physiological salt molarity and pH [see Moffett *et al.* (1993) Human Physiology (2nd Ed.) Inside cover]. Therefore the argument concerning sodium azide is not relevant.

Summary

27. Claims **1-4** are allowed.

28. Claims **150, 151, 156, 157, 162, 163, 168,** and **169** are rejected.

29. Claims **152-155, 158-161, 164-167,** and **170-172** are objected to.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
September 13, 2004

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